

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)

FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

November 24-25, 2014

DRAFT QUESTIONS

1. **DISCUSSION:** Discuss your understanding of the evidence regarding the benefits of epidural corticosteroid injection administered to reduce inflammation for pain management. Considerations in the discussion may include the following:

- a. Medical condition being treated
- b. Location of the injection
- c. Injection method
- d. Corticosteroid formulation

2. **DISCUSSION:** Discuss your understanding of the evidence regarding the risks of epidural corticosteroid injection administered to reduce inflammation for pain management, particularly the potential neurological sequelae. Considerations in the discussion may include the four factors listed in question 1 above.

3. **VOTE:** Based on your discussions of the evidence regarding the benefits and risks of epidural corticosteroid injection administered to reduce inflammation for pain management, do you recommend that FDA add a contraindication to the labeling of injectable corticosteroids for the use of these products in epidural administration?

As per 21 CFR 201.57c(5), a drug should be contraindicated only in those clinical situations for which the risk from use clearly outweighs any possible therapeutic benefit. Only known hazards, and not theoretical possibilities, can be the basis for a contraindication.

- a. **DISCUSSION:** Please explain the basis for your recommendation and any additional recommendations for other labeling changes (e.g., addition of a boxed warning, modification of the current warning statement, etc.).
4. **DISCUSSION:** Discuss any additional recommendations you have on this topic.